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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. | |
|--|-------------|--------------------------------|---------------------|------------------|--|
| 10/521,518 | 02/28/2006 | Eduard Daniel Leendert Schmidt | 294-208 PCT/US | 2030 | |
| 23869 7590 04/13/2009 HOFFMANN & BARON, LLP | | | EXAMINER | | |
| 6900 JERICHO | O TURNPIKE | | BAUM, S | BAUM, STUART F | |
| SYOSSET, NY 11791 | | | ART UNIT | PAPER NUMBER | |
| | | | 1638 | | |
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| | | | MAIL DATE | DELIVERY MODE | |
| | | | 04/13/2009 | PAPER | |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

| Application No. | Applicant(s) | | |
|-----------------|------------------------------------|--|--|
| 10/521,518 | SCHMIDT, EDUARD DANIEL LEENDERT | | |
| Examiner | Art Unit | | |
| STUART F. BAUM | 1638 | | |

| | Examiner | Art Unit | | | | | | |
|---|--|--------------------|-------------|--|--|--|--|--|
| | STUART F. BAUM | 1638 | | | | | | |
| The MAILING DATE of this communication appears on the cover sheet with the correspondence address | | | | | | | | |
| Period for Reply A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after Styf. (6) MONTH'S from the mailing date of this communication. - If NO period for reply is specified above, the maximum statutory period wit apply and will expire Styf (8) MONTH'S from the mailing date of this communication. - Failure to reply within the set or advanded period for reply will by stated can be become MARDONED (30 U.S.C. § 133). Any reply received by the Office start than three months after the mailing date of this communication, even if timely filled, may reduce any earned pattern term adjustment. See 37 CFR 1.74(b)). | | | | | | | | |
| Status | | | | | | | | |
| 1) Responsive to communication(s) filed on 18 Se | eptember 2008 and 26 January 2 | <u>009</u> . | | | | | | |
| 2a)⊠ This action is FINAL. 2b)□ This | action is non-final. | | | | | | | |
| 3) Since this application is in condition for allowar | nce except for formal matters, pro | secution as to the | e merits is | | | | | |
| closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213. | | | | | | | | |
| Disposition of Claims | | | | | | | | |
| 4)⊠ Claim(s) <u>28-33</u> is/are pending in the application | ٦. | | | | | | | |
| 4a) Of the above claim(s) is/are withdrawn from consideration. | | | | | | | | |
| 5) Claim(s) is/are allowed. | | | | | | | | |
| 6)⊠ Claim(s) <u>28-33</u> is/are rejected. | | | | | | | | |
| 7) Claim(s) is/are objected to. | | | | | | | | |
| 8) Claim(s) are subject to restriction and/or | r election requirement. | | | | | | | |
| Application Papers | | | | | | | | |
| 9)☐ The specification is objected to by the Examine | r. | | | | | | | |
| 10)⊠ The drawing(s) filed on <u>18 January 2005</u> is/are: a)⊠ accepted or b)□ objected to by the Examiner. | | | | | | | | |
| Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). | | | | | | | | |
| Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d). | | | | | | | | |
| 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152. | | | | | | | | |
| Priority under 35 U.S.C. § 119 | | | | | | | | |
| 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). | | | | | | | | |
| a) ☐ All b) ☐ Some * c) ☐ None of: | ,, | (-, (-, | | | | | | |
| 1. Certified copies of the priority documents have been received. | | | | | | | | |
| Certified copies of the priority documents have been received in Application No | | | | | | | | |
| 3. Copies of the certified copies of the priority documents have been received in this National Stage | | | | | | | | |
| application from the International Bureau (PCT Rule 17.2(a)). | | | | | | | | |
| * See the attached detailed Office action for a list of the certified copies not received. | | | | | | | | |
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| | | | | | | | | |
| Attachment(s) | | | | | | | | |
| Notice of References Cited (PTO-892) | 4) Interview Summary | | | | | | | |
| Notice of Draftsperson's Patent Drawing Review (PTO-948) Notice of Draftsperson's Patent Drawing Review (PTO-948) Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Da 5) Notice of Informal P | | | | | | | |
| Paper No(s)/Mail Date 10/1/2008. | 6) Other: | | | | | | | |

Part of Paper No./Mail Date 20090406

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DETAILED ACTION

1. The amendment filed 9/18/2008 and 1/26/2009 have been entered.

Claims 28-33 are pending.

Claims 1-27 have been canceled.

Claims 28-33 have been newly added and are drawn to the elected invention.

3. Claims 28-33 including SEQ ID NO:46 are examined in the present office action.

4. Rejections and objections not set forth below are withdrawn.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

 Claim 28 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 28 is indefinite for reciting "increasing or decreasing development" and "increases the development" and "decreases the development". Applicants have not defined what is meant by "increasing or decreasing development" and "increases the development" and "decreases the development".

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Scope of Enablement

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 28-33 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of increasing organ size and increasing the rate of cell division comprising transforming a plant with SEQ ID NO:46 operably linked to a constitutive promoter or a method of decreasing organ size and decreasing the rate of cellular division comprising SEQ ID NO:46 operably linked to a promoter in antisense orientation does not reasonably provide enablement for a method for increasing or decreasing development of a plant comprising increasing or decreasing expression of a RKS4 gene in plant or plant cell by recombinant means, wherein said RKS4 gene comprises SEQ ID NO:46 or a method for providing pathogen resistance to a plant or plant cell comprising increasing expression of a RKS4 gene in a plant or plant cell by recombinant means wherein said RKS4 gene comprises SEQ ID NO:46. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The claimed invention is not supported by an enabling disclosure taking into account the Wands factors. In re Wands, 858/F.2d 731, 8 USPQ2d 1400 (Fed. Cir. 1988). In re Wands lists a number of factors for determining whether or not undue experimentation would be required by one skilled in the art to make and/or use the invention. These factors are: the quantity of

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experimentation necessary, the amount of direction or guidance presented, the presence or absence of working examples of the invention, the nature of the invention, the state of the prior art, the relative skill of those in the art, the predictability or unpredictability of the art, and the breadth of the claim.

The claims are drawn to a method for increasing or decreasing development of a plant or plant cell comprising increasing or decreasing expression of a RKS4 gene in a plant or plant cell by recombinant means, wherein said RKS4 gene comprises SEQ ID NO:46 or method for providing pathogen resistance to a plant or plant cell comprising increasing expression of a RKS4 gene in a plant or plant cell by recombinant means, wherein said RKS4 gene comprises SEQ ID NO:46.

Applicants disclose the *Arabidopsis* cDNA sequence for RKS4 as SEQ ID NO:46 (page 64-65). Applicants disclose *Arabidopsis* and *Nicotiana tabacum* plants transformed with either an overexpression construct or antisene construct of the full length RKS4 cDNA operably linked to the 35S promoter. Plants comprising the overexpression construct exhibited increased size of organs and an increase growth rate while plants comprising the antisense construct exhibited a dwarf phenotype in which all plant organs showed a decrease in organ size and growth rate (page 106, lines 6-24).

The Office contends Applicants are not enabled for any recombinant means. The Office contends Applicants have only transformed a plant with either an overexpression construct or antisense construct. Any recombinant means encompasses for example, transforming a plant with an enhancer or suppressor of SEQ ID NO:46 expression. Applicants have not disclosed any enhancers or suppressors of SEQ ID NO:46 expression. The state-of-the-art is silent about

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enhancers or suppressors of SEQ ID NO:46. Therefore, Applicants are not enabled for any recombinant means.

Transforming a plant with a protein kinase produces unpredictable results. Christensen et al (2000, Cell 100:469-478) teach that the PID nucleic acid encodes a plant-specific serine-threonine protein kinase and that said protein kinase regulates both the "mitogenic effects of auxin in the control of lateral meristem outgrowth and its morphogenic effects during embryogenesis and vascular patterning" (page 475, left column, 2nd paragraph). Given the broad roles plant kinases play in plant biological processes, Applicants have not addressed how one controls pathogen resistance by overexpressing the RKS4 cDNA.

In the absence of guidance, undue trial and error experimentation would be required for one of ordinary skill in the art to screen through a multitude of plants that have been transformed with a multitude of constructs that are encompassed by the recitation "recombinant means" and to screen the multitude of plants using a non-disclosed assay to identify those plants, if any, that exhibit increased development or decreased development or pathogen resistance.

Therefore, given the breadth of the claims; the lack of guidance and examples; the unpredictability in the art; and the state-of-the-art as discussed above, undue experimentation would be required to practice the claimed invention, and therefore the invention is not enabled.

7. Claims 28-33 are deemed free of the prior art, given the failure of the prior art to teach or reasonably suggest a method of increasing organ size and increasing the rate of cell division comprising transforming a plant with SEQ ID NO:46 operably linked to a constitutive promoter or a method of decreasing organ size and decreasing the rate of cellular division comprising SEO.

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ID NO:46 operably linked to a promoter in antisense orientation or method of providing pathogen resistance to a plant comprising transforming a plant with SEQ ID NO:46 operably linked to a constitutive promoter.

- No claims are allowed.
- Applicant's amendment necessitated the new ground(s) of rejection presented in this
 Office action. Accordingly, THIS ACTION IS MADE FINAL. See MPEP § 706.07(a).
 Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

 Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stuart F. Baum whose telephone number is 571-272-0792. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached at 571-272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571-272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Stuart F. Baum/ Stuart F. Baum Ph.D. Primary Examiner Art Unit 1638 April 6, 2009